

Remarks

Applicant respectfully traverses the restriction requirements set forth in the Office Action of July 1, 2004.

This application was filed as a national phase application under the PCT. The application was originally filed in Europe and has German inventors.

The Examiner has applied the unity of invention rules under the PCT to examine the claims in the U.S. application. As a result, she has applied PCT Rule 13.2 to hold that there is no “technical relationship” among the eight groups set forth in the restriction requirement. Rule 13.2 states, however, “The expression ‘special technical features’ shall mean those technical features that define a contribution which each of the claimed inventions, *considered as a whole*, makes over the prior art.” (emphasis added).

Considered as a whole, the claims have a special technical feature that unify the claims. The application as a whole is directed at an approach to identifying and destroying a virulent family of nematodes responsible for causing a great deal of harm. The approach involves identifying the species of nematode attacking an animal and providing the correct countermeasure to protect the animal. Each of the eight groups is related to this approach to fighting the Strongylidae family of nematodes. Each group focuses even further on the β -tubulin found in Strongylidae nematodes. Group 1 relates to DNA sequences useful in identifying Strongylidae nematodes and to vectors and host

cells containing these sequences. Groups 2 and 3 claim polypeptides and methods for making polypeptides derived from these sequences. Groups 4, 5, and 6 are directed to the processes involved in developing a vaccine against these nematodes and Groups 7 and 8 are directed to agents that can directly attack the β -tubulin.

Under 35 U.S.C. § 372 (b) (2), the Director may “cause the question of unity of invention to be reexamined under section 121 of this title, within the scope of the requirements of the treaty and the Regulations.” Whether this statute requires the Examiner to apply the PCT rules or the Section 121 restriction requirement rules is unclear. The basic mandate of section 372 (a) is “All questions of substance and, within the scope of the requirements of the treaty and Regulations, procedure in an international application designating the United States shall be determined as in the case of national applications regularly filed in the Patent and Trademark Office.” Thus, even with the provisions of section 372 (b) (2), the typical restriction requirement rules may apply. Under typical restriction requirement rules, the restriction requirement would also be improper because the field is very easy for the Examiner to search. Tubulins are a small family of materials designed to form tubules in an organism. These materials are not as broad as, for example, proteases. The Strongylidae family of nematodes is also a much narrower field of search than, for example, mammals. Thus, the Examiner should be readily able to search the field, especially since references discussing tubulin DNA would almost certainly also discuss the protein formed by the DNA sequence.

The election of species is also respectfully traversed. Under M.P.E.P. § 803.04, a “reasonable number” of nucleotide sequences may be claimed in a single application.

Normally, ten sequences constitute a reasonable number for examination purposes. *Id.* Thus, “up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. *Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.*” *Id.* Eleven sequences of the claimed invention are a “reasonable number” to search in this application. Even if the sequences are patentably distinct, the close functional relationships of the sequences suggests that the sequences should not be made the subject of a restriction requirement.

Withdrawal of the restriction requirement and allowance of the claims is respectfully requested.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Richard S. Bullitt", with a long horizontal flourish extending to the right.

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